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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,151	01/17/2001	Gilbert R. Gonzales	UNSP/ 04	6299

7590                    09/19/2002

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EXAMINER	
RAMANA, ANURADHA	
ART UNIT	PAPER NUMBER

3751  
DATE MAILED: 09/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/765,151	GONZALES ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Anu Ramana	3751

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-27 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1-27 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. 
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in –

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

*Claims 15, 18, 19, 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Pather et al.*

Pather et al. disclose an orally administrable composition (col. 5, lines 26-28) containing a coloring agent such as carmine, F.D.&C. dyes etc. (col. 5, lines 1-6). Note that coloring agents used in orally administrable compositions act as markers by coloring or staining a portion of the oral/pharyngeal cavity.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

*Claims 1-14, 16, 17, 20, 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pather et al. in view of Kell.*

The application of the Pather et al. reference was previously discussed. Further, regarding claims 16 and 17, Pather et al. does not disclose how a marker is applied to the orally administrable composition.

Kell teaches the use of a marker for monitoring patient compliance with medication prescriptions (col. 4, lines 19-22, lines 37-41 and lines 47-53) wherein the marker is added to the medical formulation by mixing homogeneously or interspersing throughout the formulation or as a film or coating on a tablet or capsule for introduction into the body of the patient.

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the coloring agent or marker of Pather et al. as a coating or film, i.e., applied to an outer surface, or interspersing throughout the formulation or composition as taught by Kell for introduction into the body of the patient.

Regarding claim 20, Kell also teaches the use of markers that have biological half-lives between 24 to 48 hours so that they appear in the patient's urine long after ingestion, i.e., the half-life of the marker is comparable to the life of the medication in the human system (col. 5, lines 27-30).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a marker with the a half-life comparable to the life of the medication in the human system as taught by Kell in the composition of Pather et al. for the purpose of identification of the ingested medication.

Regarding claim 23, Kell teaches the use of a separate marker in association with each prescribed medication (col. 5, lines 25-27).

Regarding claim 24, the purpose of markers is to indicate that a particular drug has been ingested. This requires a correlation between the marker and the ingested drug, i.e., the time of expiration of the marker would be dependent on the time of expiration of the drug.

Regarding claim 25, the use of separate markers as taught by Kell necessitates that the markers be independently verifiable. Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided separate markers as taught by Kell in the composition of Pather et al. so that the markers are independently verifiable by the associated coloring or staining of the oral or pharyngeal cavity.

Regarding claims 26 and 27, it is well known that separate markers such as dyes cause unique coloring or staining that be visually observed. Further, it is well known that some dyes are fluorescent, a property which is visually detectable in the presence of light of a particular wavelength.

Method claims 1-14 are rendered obvious in view of the above rejections as a normal mode of operation of the Pather/Kell device as claimed.

Regarding claim 3, a placebo is well known in drug trials wherein the patient is told that the "placebo" is a drug and is treated like a drug. Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a marker for a placebo in a drug trial for introducing the "placebo" as an actual drug.

Regarding claim 4, note the oral/pharyngeal cavity is recessed and must be illuminated for observation.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Evenstad et al.: Col. 7, line 63

Neely et al.: Col. 17, lines 1-3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached on 8:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Huson can be reached on (703) 308-2580. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0975.

AR  
September 17, 2002

GREGORY HUSON  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700